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| 10/549,932 | 09/20/2005 | Ichiro Miki | 00005.001273 | 7509 |

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FITZPATRICK CELLA HARPER & SCINTO
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NEW YORK, NY 10112

| EXAMINER |
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RAMACHANDRAN, UMAMAHESWARI

| ART UNIT | PAPER NUMBER |
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1617

| MAIL DATE | DELIVERY MODE |
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09/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--|------------------------------------|--|
| Office Action Summary | Application No. 10/549,932 | Applicant(s) MIKI ET AL. | |
| | Examiner Umamaheswari Ramachandran | Art Unit 1617 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-16, 18-20 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-16, 18-20, 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner notes the receipt of the amendments and remarks received in the office on 6/18/2007 amending claims 1-10, 12-16, 18-20, 25. Claims 11, 17, 21-24, 26-27 have been canceled. Claims 1-10, 12-16, 18-20, 25 are pending and are being examined on the merits herein.

Response to Remarks

Applicants' arguments filed 6/18/2007 regarding the objection to claim 1 have been fully considered and they are persuasive. Accordingly, the objection to claim 1 is withdrawn. The double patenting rejections, 112(1), 112(2), 102(b) rejections presented in the Office Action mailed 12/18/2006 are rendered moot due to the amendment and cancellation of claims. The amendment of claims necessitated the new ground(s) of rejection presented in this Office action. The office action is made Final.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 12-14, 16, 18-20, 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compound 1 and 2 (specification, page 21) in a method of treatment of alleviating cough does not reasonably provide enablement of treatment of alleviating cough with any other compound of formula I, Ia, and Ib listed in claims 1, 2 and 16 respectively. The specification enables the treatment of alleviation of cough with compounds 1 and 2 of

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formula I where X1-X2-X3 in the formula is represented by CR5=CR6-S. Compounds of formula Ia and Ib are compounds of formula I where X1-X2-X3 in the formula is represented by CR5=CR6-O. Compounds of formula Ia and Ib are structurally and functionally distinct and hence the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the Invention:

The rejected claim is drawn to a method for alleviation of cough comprising administering compounds of formula listed in claims 1, 2 and 16.

(2) Breadth of the claims:

Claims 1, 2 and 16 are broad as they are drawn to a method for alleviation of cough comprising administering compounds of formula listed in claims 1, 2 and 16. The

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complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims.

(3) Guidance of the Specification:

The guidance given by the specification for alleviation of cough comprising administering compounds of formula listed in claims 1, 2 and 16 is for compounds 1 and 2.

(4) Working Examples:

The specification provides examples for the method of alleviation of cough comprising administering compounds 1 and 2 (specification, page 21).

(5) The relative skill of those in the art:

The relative skill of those in the medical treatment art is high, requiring advanced education and training.

(6) The predictability of art:

Claims 1, 2 and 16 are drawn to a method for alleviation of cough comprising administering compounds of formula listed in claims 1, 2 and 16. The claims are so broad and there is a high degree of unpredictability involved. Despite the advanced training in the medical treatment arts, the arts are highly unpredictable.

(7) The Quantity of Experimentation Necessary:

In order to practice the above claimed invention, one of skill in the art would have to first envision formulation, dosage, duration, route and, in the case of human treatment, an appropriate animal model system to test all the compounds of formula listed in claims 1, 2 and 16 to determine whether or not they are useful in the alleviation

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of cough. If unsuccessful, one of skill in the art would have to envision a modification in the formulation, dosage, duration, route of administration etc. and appropriate animal model system, or envision an entirely new combination of the above and test the system again. The specification enables the treatment of alleviation of cough with compounds 1 and 2 of formula I where X1-X2-X3 in the formula is represented by CR5=CR6-S.

Compounds of formula Ia and Ib are compounds of formula I where X1-X2-X3 in the formula is represented by CR5=CR6-O. Compounds of formula Ia and Ib are structurally and functionally distinct. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention of comprising administering every single compound of formula listed in claims 1, 2 and 16. *Genetech*, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10, 12-16, 18-20, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikemura et al. (WO 2005/011674, effective filing date 5/8/2003) in view of Corrao (Compr Ther. 1982, mar 8(3), 22-6).

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Ikemura et al. teach the compounds of formula I, Ia, and Ib listed in claims 1, 2 and 16 as a preventive or therapeutic agents for bronchial asthma (p 20 , claim 1, p 25 claims 30-32).

The reference do not teach the compounds in a method of treatment of alleviating cough.

Corrao teach that chronic cough is a manifestation of bronchial asthma and cough is related to pathophysiology of bronchial asthma (See Abstract).

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer tricyclic compounds of formula I, Ia, and Ib in the treatment of alleviating cough. The motivation to do so is provided by Corrao. The reference teach that cough is related to pathophysiology of bronchial asthma and it is a manifestation of bronchial asthma. It would have been obvious to one of ordinary skill in the art at the time of the invention to administer tricyclic compounds of the instant application to treat cough as it is related to bronchial asthma. One of ordinary skill in the art would have been motivated by expectation of success because of the teachings of Carrao and to provide effective therapeutic treatment in the alleviation of cough.

Response to Arguments

Applicant's amendments necessitated the withdrawal of all the rejections presented in the office action mailed 12/18/2007 and new grounds of rejection are presented in this office action.

Conclusion

No claims are allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

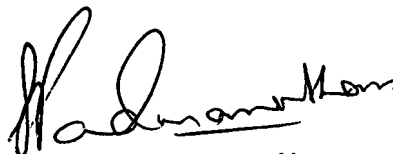
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



SREENI FADMANABHAN
SUPERVISORY PATENT EXAMINER